

Claims:

1. A method of treating or delaying the progression or onset of diabetes in a mammal comprising:
 - (a) identifying a mammal with an above-normal blood level of an inflammation marker protein; and
 - (b) administering to the mammal a therapeutically effective amount of an inhibitor of α_1 -antitrypsin.
2. The method of claim 1 wherein the step of identifying includes performing an immunoassay, a Western blot analysis, or a chromatographic separation of a sample of the mammal's blood.
3. The method of claim 1 wherein the mammal is a human.
4. The method of claim 3 wherein the method is effective to maintain the human's blood glucose level below 10 mM.
5. The method of claim 3 wherein the method is effective to maintain the human's blood glucose level between 4 mM and 6 mM.
6. The method of claim 1 wherein the inflammation marker protein is α_1 -antitrypsin, C-reactive protein, interleukin-6 or a combination thereof.
7. The method of claim 1 wherein the inflammation marker protein is α_1 -antitrypsin, the mammal is a human, and the above-normal blood level is greater than 1.3 mg α_1 -antitrypsin / mL blood.
8. The method of claim 1 wherein the inhibitor of α_1 -antitrypsin is gemfibrozil or an active derivative thereof.
9. The method of claim 8 wherein the mammal is a human, and wherein the therapeutically effective amount of gemfibrozil is about 300 to 1500 mg per day.
10. The method of claim 8 wherein gemfibrozil is administered orally.

11. The method of claim 8 wherein gemfibrozil is administered daily, and the amount of gemfibrozil is adjusted daily to maintain a normal blood level of α_1 -antitrypsin.
12. The method of claim 8 wherein gemfibrozil is administered once per day.
13. The method of claim 1 wherein the inhibitor of α_1 -antitrypsin is lithocholic acid or an active derivative thereof.
14. The method of claim 1 wherein the method further comprises the step of:
 - (c) co-administering to the mammal an anti-diabetic medicament.
15. The method of claim 14 wherein the anti-diabetic medicament includes insulin.
16. The method of claim 14 wherein the anti-diabetic medicament comprises an insulin secretagogue, a biguanide, an inhibitor of α -glucosidase, a thiazolidinedione, or a combination thereof.
17. The method of claim 14 wherein the anti-diabetic medicament comprises human placental alkaline phosphatase.
18. The method of claim 1 wherein the method further comprises the step of:
 - (d) administering to the mammal an anti-inflammatory agent.
19. The method of claim 18 wherein the anti-inflammatory agent is a non-steroidal anti-inflammatory drug, acetylsalicylic acid, ibuprofen, or an active derivative thereof.
20. The method of claim 18 wherein the anti-inflammatory agent is a cyclooxygenase-2 inhibitor.
21. A method of enhancing or restoring the sensitivity of a mammal to the metabolic actions of insulin comprising:
 - (a) identifying a mammal with an above-normal blood level of an inflammation marker protein; and
 - (b) administering to the mammal an inhibitor of α_1 -antitrypsin sufficient to

- enhance or restore the sensitivity of the mammal to the metabolic actions of insulin.
22. The method of claim 21 wherein the step of identifying includes performing an immunoassay, a Western blot analysis, or a chromatographic separation of a sample of the mammal's blood.
 23. The method of claim 21 wherein the mammal is a human.
 24. The method of claim 23 wherein the method is effective to maintain the human's blood glucose level below 10 mM.
 25. The method of claim 23 wherein the method is effective to maintain the human's blood glucose level between 4 mM and 6 mM.
 26. The method of claim 21 wherein the inflammation marker protein is α_1 -antitrypsin, C-reactive protein, interleukin-6 or a combination thereof.
 27. The method of claim 21 wherein the inflammation marker protein is α_1 -antitrypsin, the mammal is a human, and the above-normal blood level of α_1 -antitrypsin is greater than 1.3 mg α_1 -antitrypsin / mL blood.
 28. The method of claim 21 wherein the inhibitor of α_1 -antitrypsin is gemfibrozil or an active derivative thereof.
 29. The method of claim 28 wherein the mammal is a human, and wherein the therapeutically effective amount of gemfibrozil is about 300 to 1500 mg per day.
 30. The method of claim 28 wherein gemfibrozil is administered orally.
 31. The method of claim 28 wherein gemfibrozil is administered daily, and the amount of gemfibrozil is adjusted daily to maintain a normal blood level of α_1 -antitrypsin.
 32. The method of claim 28 wherein gemfibrozil is administered once per day.
 33. The method of claim 21 wherein the inhibitor of α_1 -antitrypsin is lithocholic acid or an active derivative thereof.

34. The method of claim 21 wherein the method further comprises the step of:
 - (c) co-administering to the mammal an anti-diabetic medicament.
35. The method of claim 34 wherein the an anti-diabetic medicament includes insulin.
36. The method of claim 34 wherein the anti-diabetic medicament comprises an insulin secretagogue, a biguanide, an inhibitor of α -glucosidase, a thiazolidinedione, or a combination thereof.
37. The method of claim 34 wherein the anti-diabetic medicament comprises human placental alkaline phosphatase.
38. The method of claim 21 wherein the method further comprises the step of:
 - (d) administering to the mammal an anti-inflammatory agent.
39. A method of enhancing or restoring the sensitivity of a diabetic human to the metabolic actions of insulin comprising:
 - (a) identifying a diabetic human with an above-normal blood level of an inflammation marker protein; and
 - (b) administering to the diabetic human a therapeutically effective amount of an inhibitor of α_1 -antitrypsin sufficient to enhance or restore the sensitivity of the diabetic human to the metabolic actions of insulin.
40. The method of claim 39 wherein the step of identifying includes performing an immunoassay, a Western blot analysis, or a chromatographic separation of a sample of the human's blood.
41. The method of claim 39 wherein the method is effective to maintain the human's blood glucose level below 10 mM.
42. The method of claim 39 wherein the method is effective to maintain the human's blood glucose level between 4 mM and 6 mM.
43. The method of claim 39 wherein the inflammation marker protein is α_1 -antitrypsin, C-reactive protein, interleukin-6 or a combination thereof.

44. The method of claim 39 wherein the inflammation marker protein is α_1 -antitrypsin, and the above-normal blood level of α_1 -antitrypsin is greater than 1.3 mg α_1 -antitrypsin / mL blood.
45. The method of claim 39 wherein the inhibitor of α_1 -antitrypsin is gemfibrozil or an active derivative thereof.
46. The method of claim 45 wherein the mammal is a human, and wherein the therapeutically effective amount of gemfibrozil is about 300 to 1500 mg per day.
47. The method of claim 45 wherein gemfibrozil is administered orally.
48. The method of claim 45 wherein gemfibrozil is administered daily and the amount of gemfibrozil is adjusted daily to maintain a normal blood level of α_1 -antitrypsin.
49. The method of claim 45 wherein gemfibrozil is administered once per day.
50. The method of claim 39 wherein the inhibitor of α_1 -antitrypsin is lithocholic acid or an active derivative thereof.
51. The method of claim 39 wherein the method further comprises the step of:
 - (c) co-administering to the human an anti-diabetic medicament.
52. The method of claim 51 wherein the anti-diabetic medicament includes insulin.
53. The method of claim 51 wherein the anti-diabetic medicament comprises an insulin secretagogue, a biguanide, an inhibitor of α -glucosidase, a thiazolidinedione, or a combination thereof.
54. The method of claim 51 wherein the anti-diabetic medicament comprises human placental alkaline phosphatase.
55. The method of claim 39 wherein the method further comprises the step of:
 - (d) administering to the human an anti-inflammatory agent.
56. A treatment regimen for delaying the onset of diabetes in a mammal comprising:
 - (a) identifying a non-diabetic mammal with an above-normal blood level of

- an inflammation marker protein; and
- (b) periodically administering to the mammal an inhibitor of α_1 -antitrypsin.
57. The treatment regimen of claim 56 wherein the step of identifying includes performing an immunoassay, a Western blot analysis, or a chromatographic separation of a sample of the mammal's blood.
58. The treatment regimen of claim 56 wherein the mammal is a human.
59. The treatment regimen of claim 58 wherein the method is effective to maintain the human's blood glucose level below 10 mM.
60. The treatment regimen of claim 58 wherein the method is effective to maintain the human's blood glucose level between 4 mM and 6 mM.
61. The treatment regimen of claim 56 wherein the inflammation marker protein is α_1 -antitrypsin, C-reactive protein, interleukin-6 or a combination thereof.
62. The treatment regimen of claim 56 wherein the inflammation marker protein is α_1 -antitrypsin, the mammal is a human, and the above-normal blood level of α_1 -antitrypsin is greater than 1.3 mg α_1 -antitrypsin / mL blood.
63. The treatment regimen of claim 56 wherein the inhibitor of α_1 -antitrypsin is gemfibrozil or an active derivative thereof.
64. The treatment regimen of claim 63 wherein the mammal is a human, and wherein the amount of gemfibrozil is about 300 to 1500 mg per day.
65. The treatment regimen of claim 63 wherein gemfibrozil is administered orally.
66. The treatment regimen of claim 63 wherein gemfibrozil is administered daily and the amount of gemfibrozil is adjusted daily to maintain a normal blood level of α_1 -antitrypsin.
67. The treatment regimen of claim 63 wherein gemfibrozil is administered once per day.

68. The treatment regimen of claim 56 wherein the inhibitor of α_1 -antitrypsin is lithocholic acid or an active derivative thereof.
69. The treatment regimen of claim 56 wherein the treatment regimen further comprises the step of:
 - (c) co-administering to the mammal an anti-diabetic medicament.
70. The treatment regimen of claim 69 wherein the anti-diabetic medicament includes insulin.
71. The treatment regimen of claim 69 wherein the anti-diabetic medicament comprises an insulin secretagogue, a biguanide, an inhibitor of α -glucosidase, a thiazolidinedione, or a combination thereof.
72. The treatment regimen of claim 69 wherein the anti-diabetic medicament comprises human placental alkaline phosphatase.
73. The treatment regimen of claim 56 wherein the treatment regimen further comprises the step of:
 - (d) administering to the mammal an anti-inflammatory agent.
74. A treatment regimen for treating the progression of diabetes in a mammal comprising:
 - (a) identifying a diabetic mammal with an above-normal blood level of an inflammation marker protein; and
 - (b) administering to the mammal a therapeutically effective amount of an inhibitor of α_1 -antitrypsin as needed.
75. The treatment regimen of claim 74 wherein the step of identifying includes performing an immunoassay, a Western blot analysis, or a chromatographic separation of a sample of the mammal's blood.
76. The treatment regimen of claim 74 wherein the mammal is a human.
77. The treatment regimen of claim 76 wherein the method is effective to maintain the human's blood glucose level below 10 mM.

78. The treatment regimen of claim 76 wherein the method is effective to maintain the human's blood glucose level between 4 mM and 6 mM.
79. The treatment regimen of claim 74 wherein the inflammation marker protein is α_1 -antitrypsin, C-reactive protein, interleukin-6 or a combination thereof.
80. The treatment regimen of claim 74 wherein the inflammation marker protein is α_1 -antitrypsin, the mammal is a human, and the above-normal blood level of α_1 -antitrypsin is greater than 1.3 mg α_1 -antitrypsin / mL blood.
81. The treatment regimen of claim 74 wherein the inhibitor of α_1 -antitrypsin is gemfibrozil or an active derivative thereof.
82. The treatment regimen of claim 81 wherein the mammal is a human, and wherein the therapeutically effective amount of gemfibrozil is about 300 to 1500 mg per day.
83. The treatment regimen of claim 81 wherein gemfibrozil is administered orally.
84. The treatment regimen of claim 81 wherein gemfibrozil is administered daily, and the amount of gemfibrozil is adjusted daily to maintain a normal blood level of α_1 -antitrypsin.
85. The treatment regimen of claim 81 wherein gemfibrozil is administered once per day.
86. The treatment regimen of claim 74 wherein the inhibitor of α_1 -antitrypsin is lithocholic acid or an active derivative thereof.
87. The treatment regimen of claim 74 wherein the treatment regimen further comprises the step of:
 - (c) co-administering to the mammal an anti-diabetic medicament.
88. The treatment regimen of claim 87 wherein the anti-diabetic medicament includes insulin.

89. The treatment regimen of claim 87 wherein the anti-diabetic medicament comprises an insulin secretagogue, a biguanide, an inhibitor of α -glucosidase, a thiazolidinedione, or a combination thereof.
90. The treatment regimen of claim 87 wherein the anti-diabetic medicament comprises human placental alkaline phosphatase.
91. The treatment regimen of claim 74 wherein the method further comprises the step of:
 - (d) administering to the mammal an anti-inflammatory agent.
92. The treatment regimen of claim 74 wherein the treatment regimen further comprises the step of:
 - (e) monitoring the level of α_1 -antitrypsin in the mammal's blood.
93. Use of an inhibitor of α_1 -antitrypsin for the manufacture of a medicament for treating or delaying the progression or onset of diabetes.
94. Use of gemfibrozil for the manufacture of a medicament for treating or delaying the progression or onset of diabetes.
95. Use of lithocholic acid for the manufacture of a medicament for treating or delaying the progression or onset of diabetes.
96. Use of an inhibitor of α_1 -antitrypsin for the manufacture of a medicament for enhancing or restoring the sensitivity of a mammal to the metabolic actions of insulin.
97. Use of gemfibrozil for the manufacture of a medicament for enhancing or restoring the sensitivity of a mammal to the metabolic actions of insulin.
98. Use of lithocholic acid for the manufacture of a medicament for enhancing or restoring the sensitivity of a mammal to the metabolic actions of insulin.
99. A combination of agents for simultaneous, separate, or sequential use for treating or delaying the progression or onset of diabetes, comprising:

a therapeutically effective amount of an inhibitor of α_1 -antitrypsin; and
an anti-inflammatory agent.

100. The combination of claim 99, wherein the inhibitor of α_1 -antitrypsin is gemfibrozil.
101. The combination of claim 99, wherein the inhibitor of α_1 -antitrypsin is lithocholic acid.
102. The combination of claim 99, wherein the anti-inflammatory agent is a non-steroidal anti-inflammatory drug.
103. A combination of agents for simultaneous, separate, or sequential use for treating or delaying the progression or onset of diabetes, comprising:
a therapeutically effective amount of an inhibitor of α_1 -antitrypsin; and
an anti-diabetic medicament.
104. The combination of claim 103, wherein the inhibitor of α_1 -antitrypsin is gemfibrozil.
105. The combination of claim 103, wherein the inhibitor of α_1 -antitrypsin is lithocholic acid.
106. The combination of claim 103, wherein anti-diabetic medicament is insulin.
107. The combination of claim 103, wherein anti-diabetic medicament is human placental alkaline phosphatase.
108. A method for identifying a subject in need of therapy for treating or delaying the progression or onset of diabetes by administration of an inhibitor of α_1 -antitrypsin, comprising:
measuring *in vitro* the level of an inflammation marker protein in a sample of the subject's blood; and
determining whether the measured level is an above-normal blood level of the inflammation marker protein.

109. The method of claim 108, wherein the step of measuring includes using an immunoassay kit.
110. The method of claim 108, wherein the step of measuring includes using a radial immunodiffusion assay kit.
111. The method of claim 108, wherein the step of measuring includes using a Western blot analysis kit.
112. Use of an assay kit for the identification of a subject in need of therapy for treating or delaying the progression or onset of diabetes by administration of an inhibitor of α_1 -antitrypsin, wherein the use includes measuring the level of an inflammation marker protein in a sample of the subject's blood.
113. The use of claim 112, wherein the inflammation marker protein is α_1 -antitrypsin.
114. The use of claim 112, wherein the assay kit is an immunoassay kit.
115. The use of claim 112, wherein the assay kit is a radial immunodiffusion assay kit.
116. The use of claim 112, wherein the assay kit is a Western blot analysis kit.